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December 1, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. : 97N-484S

To Whom It May Concern:

I am writing this letter in support of allowing physicians to continue to use bone allograft without this item coming under regulation by the FDA.

We have used this material for many years without adverse effect. In a very large number of cases, we have never had a problem involving rejection or immune response to an allograft.

Many of the companies who are involved in supplying allograft are small companies and probably don't have the resources to supply extensive documentation for their product to the FDA. Loss of this product from the market will mean that patients will now have to have bone taken from their hip. I can tell you based on personal experience that this can result in an extremely painful postoperative course. In fact, patients seldom complain of the primary operative site in the neck, but go on to have complaints referable to the donor bone graft site for months. Some of them never get over their complaints at the hip donor site. Furthermore, I have had occasion to take patients back to the operating room for hematoma and infection in the hip donor site.

In view of the long record of value without risk of this product, I would strongly urge you not to involve this product in further federal regulation.

Very truly yours,

Arnold Goran, M.D.
AG/kd

Date Dictated: 11/30/99
Date Typed: 12/1/99

97N-484S

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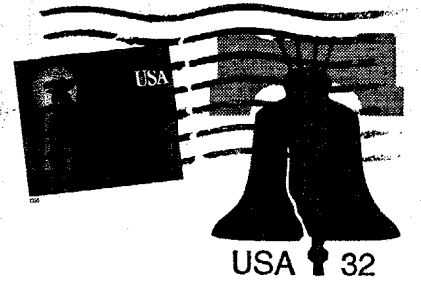

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